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TITLE: Virtual Reality and Cellular Phones as a Complementary Intervention for Veterans with PTSD and Substance Use Disorders

PRINCIPAL INVESTIGATOR: Dr. Mark Z. Rosenthal

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Annual Report

Project Title: Virtual Reality and Cellular Phones as a Complementary Intervention for Veterans with PTSD and Substance Use Disorders

Award No.: W81XWH-08-2-0209

Principal Investigator: Mark Z. Rosenthal, Ph.D.

I. Introduction

In the present project, we are testing a novel adjunctive intervention designed to complement exposure-based therapies for combat veterans with posttraumatic stress disorder (PTSD) and co-morbid substance use disorders (SUDs). The novel intervention uses virtual reality as a cue exposure platform to extinguish cravings to drug-related cues, and cellular phones as an extinction reminder platform to transfer learning effects from exposure/extinction in the clinic to adaptive responses in high-risk contexts for drug use in everyday life. It is hypothesized that: (a) the complementary intervention will be acceptable and feasible and (b) compared to participants receiving exposure therapy alone, those receiving exposure therapy plus the complementary intervention will have better treatment outcomes at post-treatment and follow-up, as evidenced by lower PTSD symptoms, less substance use, and greater retention in treatment.

II. Body

Year 3 Tasks Outlined in the Statement of Work

These tasks below were identified in the Statement of Work as active tasks for year 3 (out of a planned four year project).

Participant Recruitment

Participant recruitment began in February, 2010. Recruitment methods have included posting flyers at the Durham VAMC and at selected treatment and community centers in the Durham area, advertisements on the DUMC website and local free newspaper, and direct referrals from VA clinicians. Over the past year, we completed 152 screening phone calls, yielding 72 individuals eligible to be scheduled for a diagnostic assessment. The primary reasons for ineligibility were not having current substance use (inclusion criteria), having a trauma that was unrelated to military service (inclusion criteria), or being diagnosed with a psychotic disorder or mania (exclusion criteria). Combined with last year's recruiting, we have completed 237 screening phone calls, yielding 93 individuals who were eligible for participation. The pace of recruitment so far is adequate for reaching the study's recruitment goals. Our recruitment has improved through refinement of advertisements to better target likely eligible individuals and through increasing contacts with therapists who treat individuals who would likely be eligible for the study.

Diagnostic Evaluations

Of the 72 potential participants scheduled for diagnostic interviews over the past year, 49 completed the assessments, yielding 24 participants who were enrolled in the study. The primary reason for exclusion from the study was not meeting criteria for PTSD. In total, we have randomized 30 participants into the study; however, 8 participants did not appear for their first therapy appointment leaving 22 participants in our intent to treat (ITT) sample.

Symptom Severity Evaluations

Symptom severity measures have been completed along with the diagnostic evaluations, described above.

Urine Testing

During this year, we conducted urine sampling with enrolled study participants. Urine testing is conducted 3 times a week, as stated in the study protocol.

Treatment

Over the past year, treatment for enrolled study participants was carried out by trained study therapists. New study therapists were also trained to join the treatment team.

Data Management, Statistical Analyses, and Statistical Consultation

Data collection has continued on the project. Screening data, diagnostic and symptom severity data, urine data, and weekly therapy-related assessments have all been collected for individuals who have had contact with the project. All data is entered into statistical software within a few days of being collected. No participant names are connected to unique ID numbers across all documentation, save for a single password protected electronic file used to maintain contact information, as described in the protocol. Statistical consultation has continued between the biostatistician, Dr. Strong, and Dr. Rosenthal, to facilitate effective and accurate data collection.

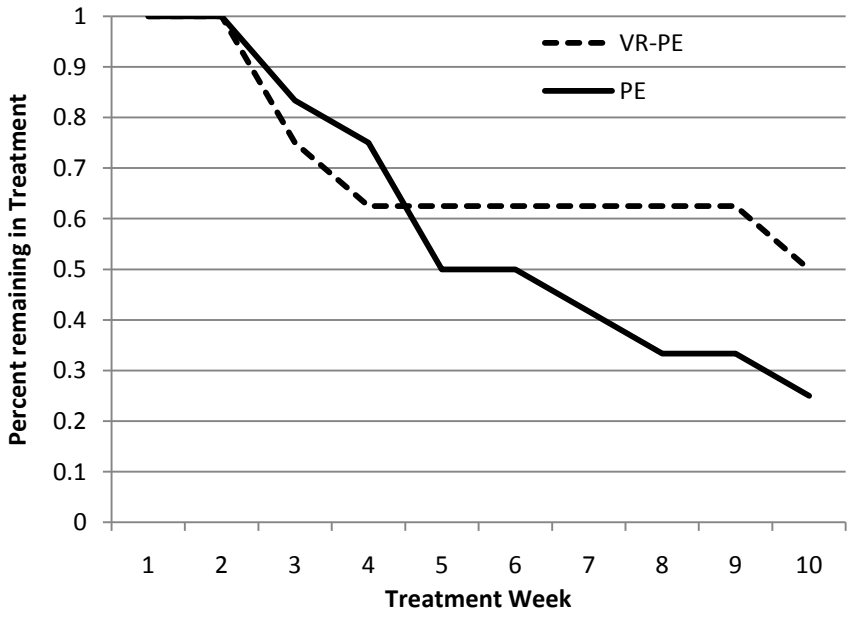
We have examined preliminary results regarding recruitment, retention, feasibility, acceptability, and outcome for the project. Of those who have completed treatment, 3 of the 8 participants (38%) assigned to the VR+PE condition dropped out of treatment, while 8/12 (66%) of participants in the PE (control) condition have dropped out, suggesting that the addition of VR to standard PE may increase retention rates. Reasons for dropout are presented in Table 1. The 2 remaining participants in the ITT sample are currently in treatment.

Table 1.

ID#	Condition	# Sessions	Reason for dropout
9005	PE	2	no reason given
9030	PE	4	did not want PE treatment after session 4
9037	PE	7	distance was too far to continue treatment
9043	PE	2	decided to start treatment at VA
9097	VR	3	Patient and therapist felt problems were too severe, started treatment at VA
9094	VR	2	did not want PE treatment after session 2
9110	PE	3	work schedule conflicted with treatment
9093	PE	6	Patient felt he was better after 6 weeks, wanted to look for a job
9103	PE	4	could not commit to PE treatment after session 4
9155	PE	4	starting work in a different state
9182	VR	2	no show after session 2

Percentage of patients remaining in treatment by condition is shown in Figure 1.

Figure 1.

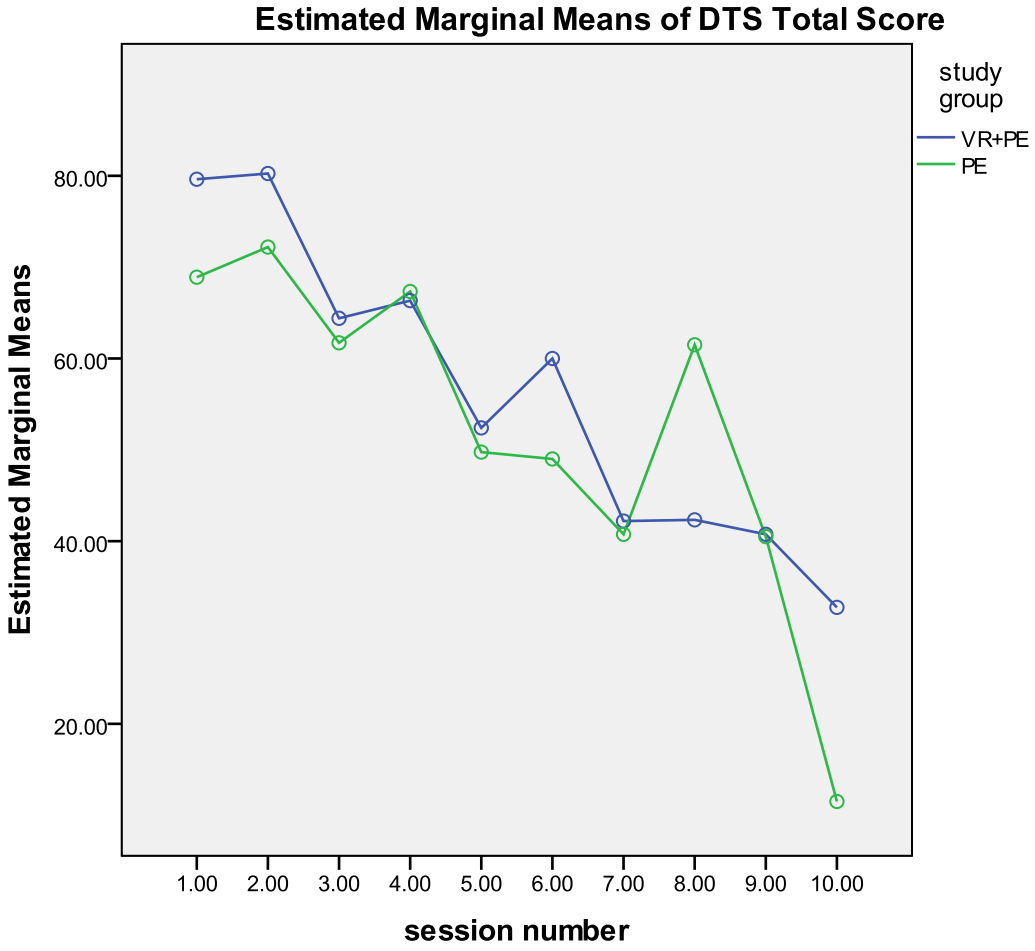


Throughout the study, 30 individuals qualified for the study (including those 8 who never initiated treatment). Among these individuals, 16 (53%) met criteria for current cigarette use , 27 (90%) met criteria for alcohol abuse or dependence, 11 (37%) met criteria for cannabis abuse or dependence, 8 (27%) met criteria for cocaine abuse or dependence, and 5 (17%) met criteria for opioid abuse or dependence.

Preliminary analyses with the Davidson Trauma Scale (DTS), a self report instrument which measures frequency and severity of PTSD symptoms indicate that both

conditions (i.e., VR+PE and PE alone) have been successful at reducing PTSD symptoms significantly over the course of the study ($F(1, 105) = 2.92$, $p = .005$). Figure 2 shows the change in DTS scores aggregated across participants in each treatment group.

Figure 2.



Mean differences in scores from pre-treatment to post-treatment for each interviewer-administered PTSD, substance abuse, or alcohol abuse outcome variable are presented in Table 2. Because too few participants have completed all assessments to make statistical analyses of difference meaningful, we present only means and standard deviations of these differences. As shown, participants have shown improvement from pre- to post-treatment on all outcome measure.

Table 2. Outcome Variable	Pretreatment M(SD)	Posttreament M(SD)
PTSD Symptoms, past month (CAPS)	82.4 (18.7)	42.9 (33.5)
Nicotine (Fagerstrom)	8.00 (3.46)	7.6 (3.86)
Alcohol use (# times in past 30 days)	7.08 (9.18)	3.17 (6.00)
Heroin use (# times in past 30 days)	1.78 (5.33)	0 (0)
Cocaine use (# times in past 30 days)	0 (0)	0 (0)
Cannabis use (# times in past 30 days)	5.30 (11.30)	0.70 (2.21)

Key Research Accomplishments

Research activities in year 3 have included:

- Training of study staff and therapists
- Continuation of recruitment and assessment
- Continuation of active treatment for participants in the study
- Continuation of data collection and data entry
- Continued regulatory review and approval of all study materials across the respective IRBs at DUMC, the Durham VAMC, and the USAMRRC.

Reportable Outcomes

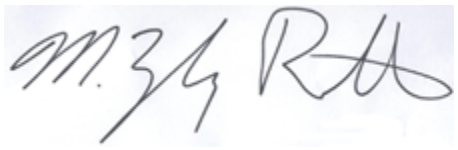
Because the study is still collecting data, there are no reportable outcomes from year 3.

Conclusions

There are no study conclusions from year 3. We anticipate study conclusions to be generated at or near the end of data collection, during year 4.

References

None



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